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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,430	08/18/1999	PAUL A. MOORE	PF466P1	6501

22195 7590 11/05/2003

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EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/376,430	Applicant(s) MOORE ET AL.	
	Examiner Eileen O'Hara	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-56,59-61,64-79,81-83 and 85-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-39,49-54,59 and 104 is/are allowed.
- 6) ☒ Claim(s) 40-48,55,56,60,61,64-79,81-83 and 85-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8/15/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 24-56, 59-61, 64-79, 81-83 and 85-104 are pending in the instant application. Claims 55, 56, 60, 61, 64, 76, 88-90, 94-96 and 100-102 have been amended as requested by Applicant in the Paper filed August 15, 2003.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.1 Claims 88, 91-94, 97-99 and 102 remain rejected under 35 U.S.C. 112, first paragraph, and claim 90 is now rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of SEQ ID NO: 2 and for polypeptides consisting of fragments of SEQ ID NO: 2, and for polypeptides having homology to the polypeptide of SEQ ID NO: 2 that have the specific activities of inhibiting the differentiation and/or proliferation of immune cells or stimulating immune cell proliferation, does not reasonably provide enablement for polypeptides encoded by a nucleic acid molecule comprising a polynucleotide which hybridizes to the cDNA in ATCC Deposit No. 209691 or 2069641 and wherein the encoded polypeptide has the activity of binding an antibody specific for a polypeptide encoded by the cDNA in ATCC Deposit No. 209691 or 2069641. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have amended claims 88 and 94 to state that the claimed polypeptides bind an antibody specific for the polypeptide of SEQ ID NO: 2. Claim 90 had previously not been rejected for this limitation; however, upon further consideration, this limitation is not sufficient to enable the claims. The specification is enabling for assays to determine if the claimed polypeptide variants have the activities of the polypeptide of SEQ ID NO: 2 (inhibiting the differentiation and/or proliferation of immune cells or stimulating immune cell proliferation), however, the specification has not taught how to use polypeptides that do not have those activities. Because claims 88 and 94 have the limitation of binding an antibody specific for a polypeptide encoded by the cDNA in ATCC Deposit No. 209691 or 2069641 as an alternative limitation from that of stimulating the differentiation and/or proliferation of immune cells, such polypeptides are not required to have the latter activities, and the specification has not taught how to use polypeptides that do not have those activities.

3.2 Claims 88, 91-94, 97-99 and 102 remain rejected under 35 U.S.C. 112, first paragraph, and claim 90 is now rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claims 88 and 94 to state that the claimed polypeptides bind an antibody specific for the polypeptide of SEQ ID NO: 2. Claim 90 had previously not been

rejected for this limitation; however, upon further consideration, this limitation is not sufficient to meet the written description guidelines.

The written description guidelines indicate that a representative species may be adequately described through its structure, through its functional characteristics, or through a combination of its structure and function. Claims 88 and 94 have the limitation of binding an antibody specific for a polypeptide encoded by the cDNA in ATCC Deposit No. 209691 or 2069641, but the specification does not have a definition for an antibody “specific” for a polypeptide. Therefore, a reasonable art accepted definition would be an antibody that would bind with higher affinity to one protein than to another. An antibody that binds with specificity to a polypeptide binds to a particular epitope, but such an epitope may also be present on an unrelated protein, and therefore a polypeptide that binds an antibody specific for a polypeptide comprising a polypeptide of SEQ ID NO: 2 does not meet the written description guidelines.

The claims do not provide adequate structure or function to meet the written description guidelines.

3.3 Claims 55, 56, 60, 61, 64-79, 81-83 and 85-102 are rejected under 35 U.S.C. 112, first paragraph, and claim 90 is now rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, because claims 55, 56, 60, 61, 64, 76, 88, 89, 94, 95 and 100-102 recite the term “upon ligand binding”. Applicants point to pages 37, 96 and 147 in the specification as providing support this term, however there is no ligand known or disclosed for

this receptor, and therefore the specification lacks written description for this limitation. This rejection would be withdrawn if the term “upon ligand binding” were deleted.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 40-48 and 103 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-48 and 103 are indefinite because claims 40 and 103 encompass a “polypeptide” that would be a single amino acid – for example, in 40 (b), the polypeptide can consist of an amino acid sequence of from amino acid residues m-n of SEQ ID NO: 2, where m is an integer in the range of +1 to +370 and n is an integer in the range of +2 to +371 – therefore the polypeptide can consist of amino acid 370, two, three, four etc. amino acids. Because claims 40 and 103 also recite the limitation that the polypeptide consist of at least seven contiguous amino acid residues of SEQ ID NO: 2, the claims are inconsistent.

It is believed that all pertinent arguments have been answered.

Conclusion

5.1 Claims 24-39, 49-54, 59 and 104 are allowed.

5.2 Claims 40-48, 55, 56, 60, 61, 64-79, 81-83 and 85-103 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.


Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600